Air Pollutants—Safe Concentrations? Introduction

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Good morning, ladies and gentlemen. Welcome to the Thursday session of Statistics and the Environment. The session this morning is entitled "Air Pollutants—Safe Concentrations?" Your program lists David Solomon as your moderator. Mr. Solomon regrets that he is not able to be with you this morning. He is out of town and I am his deputy in the Environmental Design and Control Division of the Office of Research, Federal Highway Administration. Our work is, of course, related to these subjects and we're very much interested in it.

Before introducing the first speaker, let me introduce two additional panelists. We will hold all questions until after the second speaker has finished. Our first panelist is Dr. William Kirchhoff, who is a physicist and Deputy Manager, Measures for Air Quality, National Bureau of Standards, Gaithersburg. Our second panelist is Dr. Nozer Singpurwalla, Professor of Operations Research, School of Engineering and Science, George Washington University.

Our first speaker this morning is Dr. John Finklea, an MD and a DPH who has had a wide experience throughout the years, having grown up in South Carolina and now the Director of the National Environmental Research Center, EPA at Research Triangle Park, North Carolina. It is a pleasure to welcome you, Dr. Finklea.

Auto Emissions and Public Health: Questions, Statistical Problems, and Case Studies

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Industrial nations now recognize that environmental factors are among the most important determinants of mankind's future physical and economic well-being. The effects of environmental stressors upon human health and the actions necessary to protect public health are areas of public concern and public disagreement. No environmental problem is of greater interest to the average American than the control of emissions from the nation's fleet of more than 100 million vehicles. This report will discuss the problem of determining "safe concentrations" of air pollutants in 3 stages beginning with a general overview composed of 12 key questions and their answers, progressing to a brief discussion of 6 unresolved statistical problems and ending with a review of short case studies on oxides of nitrogen and on problems engendered by oxidation catalysts. The present communication is not intended to address all of these problems in detail but rather to help the reader better understand the scientific and regulatory challenges faced by his society. The viewpoint expressed is that of a public health physician inextricably entangled in the problems described and the candid observations contained herein do not necessarily represent the official views of any agency.

Twelve Questions

The conceptual and practical scientific and regulatory problems encountered in defining and achieving "safe ambient concentrations" of pollutants emitted from automotive sources can be better understood after we provide the best available answers to the following 12 questions:

- What is a "safe level" of an air pollutant?
- What kinds of information are needed to control an air pollutant?
- How does one compensate for information gaps?
- What are the consequences of unrestrained advocacy?
- How should we assess alternate control strategies?
- What pollutants are emitted from mobile sources?
- What are the major determinants of automotive emissions?
- How well can we measure pollutants in emissions and in ambient air?
- How important are dispersion and transformation?
- How well do emissions controls work?
- How does one link pollutant emissions to human exposures?
- What should a minimally adequate health intelligence base assess?

What is a "safe level" for an air pollutant?

Scholars, scientists, public interest groups, industry and regulatory bodies each approach the definition of a "safe level" with a differing set of biases. As has been pointed out earlier in this symposium, society also lacks consistency in defining safe levels and acceptable risks across the broad range of problems which are regulated to protect the public health and welfare. For ambient air quality our society has established a clear legal directive. The Clean Air Act as amended in 1970 requires that health-related or primary air quality standards be set to protect fully the public health and that these standards contain an adequate margin of safety. This legislation requires that ambient air quality standards protect both specifically susceptible subgroups and healthy members of the population. The Act excludes severely infirmed persons who require an artificial environment. In theory, accelerated mortality of hospitalized or institutionalized patients with severe, pre-existing illnesses might not be an appropriate effect upon which to base a primary air quality standard. In practice, regulatory agencies have duly considered mortality studies. It is well known that the Clean Air Act specified rather demanding time frames for setting and achieving health-related air quality standards and emissions standards for motor vehicles. Many of you may not, however, recall that passage of the 1970 Clean Air Act amendments was preceded by a half century of lightly regarded warnings about health problems attributable to motor vehicle exhausts and 6 years of activity under the more permissive 1965 Amendments. The net result of the latter efforts was a continuing deterioration in urban air quality indices which reflected the impact of automotive emissions. The Congress also provided for careful technical and legislative review of the problems encountered in implementing their legislation. It is my opinion that any review of the "safe level" problem which isolates the issue from its legislative context is not likely to prove very useful.

At least two other approaches to the "safe level" problem are frequently espoused. They are the cost-benefit approach and a view that argues that any increase over natural background levels of a pollutant is likely to be harmful and therefore either total prohibition of pollutant emissions or maximum achievable controls should be instituted. The cost-benefit approach attempts to balance control costs against the health benefits. Such an approach is superficially attractive but it is difficult to apply. Basically it is much easier to calculate control costs than to develop the needed health damage functions. With our present limited health intelligence base and with the present methodologic difficulties in assigning and apportioning health costs, there would be a tendency to underestimate true health costs. A cost-benefit approach will require rather precise dose-response functions for each adverse effect. Such functions cannot be constructed in the next few years without a greatly increased research effort. In my opinion precipitous movement to a cost-benefit philosophy would tend to slow drastically the air pollution control effort and probably ignore a large but as yet poorly defined residual of continuing ill health. It has always seemed to me paradoxical that my colleagues who argue most forcefully for applying the cost-benefit approach in the immediate future are most often not the same individuals who support efforts to conduct the health research necessary to generate reliable health damage functions. Indeed, it often seems that advocates of the more stringent "threshold" approach are more likely to understand the need for a better health information base.

The third approach is to require total prohibition of pollutant emissions or maximum feasible controls. Among the advocates of this course there is great disagreement on how to define "feasible." Those pursuing the maximum control approach often argue that any increase in pollutant levels over natural background concentrations is harmful to the public health and welfare. The probable harmful effect of low background levels or seasonal swings in familiar environmental stressors upon especially susceptible subgroups is often cited as justification for the total prohibition or maximum feasible control approach. While it may be theoretically attractive to agree that any environmental stressor can adversely affect susceptible subgroups, there is little practical information to support this position. In fact, it is increasingly difficult to measure adverse effects upon susceptible subgroups as one approaches the primary ambient air quality standards for motor vehicle related pollutants. One also encounters tactical advocacy of the maximum feasible control philosophy among a few who really do not intend to support either the necessary efforts to develop the control technology leading to stringent emissions reduction or the necessary health research to estimate which adverse effects are really "no-threshold" problems. In fact the latter individuals are sometimes alleged to be interested in "cosmetic controls" which take advantage of a limited, technical information base to advocate measures which do little more than minimize "first costs" to special interest groups.

There may also be substantial room for honest disagreement on what constitutes an adverse health effect. In this case the problem usually involves deciding which changes in bodily function represent an increased risk for future disease or for aggravation of existing disorders and which changes are simple adaptive functions. Points of dispute are not easily resolved because pollutant exposures are not usually the sole cause of death or the sole cause of any single disease or group of disorders.

What kinds of information are needed?

Ambient air quality standards rest upon a broad interlocking scientific information base. Weaknesses in one or more of these knowledge areas may severely constrain efforts to establish a health-related air quality standard or to reduce the levels of ambient air pollution. Realistic assessment of our current information base shows that major gaps exist for each of the pollutants covered by the primary ambient air quality standards.

Scientifically defensible air pollution controls require adequate measurement methods for sources and for ambient air, emissions profiles with sufficient tempro-spatial detail to accommodate implementation planning, a reasonable understanding of pollutant transport and transformation in the atmosphere so that one can quantify the determinants of secondary pollutants generated in the atmosphere, a good air monitoring data base, dose response information linking pollutant exposures to adverse effects on health and welfare, predictive models linking emissions to air quality and to adverse effects, and viable control technologies. Without this information we must deal with major uncertainties and run substantial risks of instituting less than optimal control strategies.

How does one compensate for information gaps?

How does one compensate for information gaps when faced with legislative mandates that include demanding schedules for the promulgation of standards and institution of control measures? At least 3 options are available. In my opinion the first and most reasonable option is to initiate the required regulatory actions and to define the range of uncertainty, assess its importance and initiate the necessary research program to reduce uncertainty to tolerable levels. A second option which may be used along with the first is to include margins of safety in health-related standards to compensate for uncertainties. When one is dealing with stringent controls of emissions, safety margins are an expensive way to compensate for uncertainty. A third option is to make decisions that either ignore uncertainty or employ uncertainty in an asymmetrical fashion to support particular decisions while making serious efforts to do the research necessary to gain a more complete understanding of the problem. This brings us face to face with another question: how much information is enough? Frankly, it has been my experience that the answer is more economic than health-related. Controls that affect major, tightly organized industrial enterprises are likely to require the greatest technical justification over and above that required by any postulated adverse health effects attributable to the problem. From a public health point of view the amount of information required for a control action would depend upon the ubiquity and intensity of exposure, the severity and frequency of adverse health effects, the likelihood of interactions intensifying the effect of other major determinants of ill health and the ability of existing technology to assess the problem in question. There may be occasions when health priorities and economic priorities do not coincide.

What are the consequences of unrestrained advocacy?

Scientists and the legal profession must learn to understand each other and to work together towards solving environmental problems. Working together does not mean assuming a posture of unrestrained advocacy. In fact, unrestrained advocacy complicates and can impede efforts towards rational solutions. Scientists and lawyers should be seeking ways to make available all relevant information developed by government, industry or other groups rather than pursuing unrestrained advocacy. How much could information hidden in the files of industry and government assist our national effort to achieve rational environmental controls? I do not know the answer to this question but it is apparent that the information needs are very large and that our nation should strive to optimize its use of limited research data resources. There is also substantial danger that unrestrained advocacy might channel limited research resources into supporting an advocacy position and not towards reducing the most important areas of uncertainty. Finally, a long series of adversary actions focused on existing problems may cause us to overlook emerging problems that can be ameliorated or avoided if our efforts are more properly focused. On the other hand, there can be no doubt that poorly targeted, meandering scientific efforts not focused on adequate legal mandates will also fail to serve the best interests of our nation. We need to develop mutual understanding between scientists and lawyers to ascertain how we can attain clearly defined goals subscribed to by a consensus of our society.

How should we assess alternate control strategies?

The Clean Air Act established precise goals for the reduction of automotive emissions but allowed somewhat more flexibility in the time allowed to attain these emission reductions. Several alternate control strategies have been proposed or informally discussed by scientific panels, industrial concerns, other governmental units and by public interest groups. Usually one does not have the minimal information base necessary to evaluate alternate proposals. For each alternate control strategy one should ask and answer the following questions. What time frame is envisioned? What is the impact on fuel economy? What capital investments and consumer costs are involved? How effective is the proposed strategy when compared to other strategies? How do controls influence emissions not currently regulated? And finally, what hazards may be produced by the control strategy itself? In other words, one must understand the impact of controls not only on air quality and the economy but on overall environmental quality and public health as well. Neither the Federal government nor American industry has done a good job with these problems. Serious questions are often raised about proposed controls early in their development but these problems are too often inadequately addressed until large investments have been made. Serious current problems in both stationary and mobile source control programs could have been avoided if the environmental and public health impacts of proposed control strategies had been carefully considered. Controls based upon a fragmentary understanding of the problems one wants to correct seem the most likely to themselves produce large problems.

What pollutants are emitted from mobile sources?

The Clean Air Act specifically mandated reductions in emissions of gaseous hydrocarbons, oxides of nitrogen and carbon monoxide from light duty motor vehicles. The Act also contained specific provision for later regulation of exhaust particulate levels if this was deemed advisable and for the regulation of fuel additives and fuel composition. The Environmental Protection Agency has proposed regulations which will reduce the amount of lead in gasoline and require registration of both fuels and additives to fuels and lubricants. Small amounts of sulfur oxides and certain metals are also emitted from current vehicles. Complex exhaust particulates are usually composed of a core of lead or other metals and a shell of complex hydrocarbons. These particles are small enough to penetrate deeply into the lung. The hydrocarbons emitted and the resulting hydrocarbon shell which is formed around particulate nuclei contain a number of carcinogens and co-carcinogens. Use of fuel additives or lubricants containing other metals, for example manganese, would undoubtedly alter the structure of exhaust particulates. Emissions control systems used with current automotive power plants and the introduction of alternate power systems can further alter emissions profiles. For example, gas turbines might emit worrisome quantities of certain nickel compounds, and stratified charge and diesel engines might emit greater quantities of poorly characterized exhaust particulates. Emissions control systems also can change complex gaseous hydrocarbon profiles.

What are the major determinants of auto emissions?

Major determinants of emissions include certain characteristics of the vehicle population (age, size, power plant and growth rate), driving habits and patterns, vehicle maintenance, performance and deterioration of emission control devices, and certain characteristics of the fuels, fuel additives and lubricants utilized.

Vehicle populations, like human populations, have characteristics which vary from place to place and over time. There is currently a shift towards smaller vehicles and one may see a trend towards a longer survival of older, uncontrolled vehicles because of their somewhat greater fuel economy and possibly as a result of economic dislocations. The introduction of alternate power plants would also change emissions patterns. An even more important influence is the growth rate. Different assumptions for the growth of the vehicle population will lead to markedly different projections at the end of a decade but will not greatly influence projections for 1, 2 or 3 years. Energy constraints might be expected to slow the rate of growth for the vehicle population. Since stationary and area sources contribute significantly to hydrocarbon and nitrogen oxide emissions, the relative importance of these sources to mobile sources should be kept in mind and the expected variations of each over time considered.

Energy shortages may well change driving habits sufficiently to alter emissions projections in that the number of cold starts and the number of vehicle miles driven will probably be reduced. However, if there is a larger reduction in vehicle miles than number of trips, one may well find that the number of cold starts has been only minimally reduced. Since cold starts account for a disproportionately large fraction of the emissions measured during the currently used test cycle, adjusting emissions estimates on the basis of reductions in vehicle miles traveled overstates the effectiveness in reducing emissions. Reducing top cruising speeds on arterial thoroughfares from 60 or 70 to 50 mph will increase emissions of carbon monoxide and hydrocarbons but decrease emissions of nitrogen oxides. Overall it is difficult to predict the exact effect of likely changes in driving habits engendered by our energy shortages. In general, the direction would be to reduce emissions, especially in non-urban areas, but the reduction would not be proportionate to the reduction of vehicle miles traveled.

In the hands of consumers, control devices may be intentionally circumvented or simply deteriorate because of improper maintenance. A great deal of uncertainty surrounds the overall impact of control device deterioration. Obviously, this factor will greatly influence emissions projections.

Energy or regulatory constraints may also lead to alterations in fuel composition that could influence the reactivity of hydrocarbon emissions and the emissions of presently unregulated complex organic compounds. Similarly, fuel composition and fuel additives can affect the performance of emission control devices. The impact of such changes on each emissions category is not easy to predict at the present time.

How well can we measure pollutants in emissions and in ambient air?

In general methods for exhaust emission measurements constitute less of a problem than measuring pollutants at the lower concentrations which are found in ambient air. It is also less difficult to characterize and measure accurately a primary pollutant like carbon monoxide than transformation pollutants like the nitrogen dioxide, ozone, other oxidants and the aerosols derived from nitric oxide and sulfur oxides emissions. A final general observation is that measurement methods can always be improved. It is our opinion that measurement methods for exhaust emissions of carbon monoxide, gaseous hydrocarbons and nitrogen oxides are reasonably adequate for current vehicles but more sensitive methods may be required to monitor vehicles that meet statutory standards. Usable methods also exist for measuring emissions of exhaust particulates and metals. On the other hand, better methods are needed for exhaust aerosols and more complete characterization of exhaust particulates, aerosols and hydrocarbons is required for both exhaust streams and ambient air. Adequate methods also exist for measuring carbon monoxide and ozone in ambient air. Our present Federal Reference Method for measuring non-methane hydrocarbons in ambient air is not sufficiently sensitive as the lower detectable limit of the level approximates the ambient standard instead of being sensitive enough to measure levels only one-tenth the standard, as would be preferable. This difficulty is not of monumental importance as the ambient hydrocarbon standard is at present used only for planning purposes in the control of oxidants and not as a standard enforced because of adverse health effects attributed to hydrocarbons per se.

How important are dispersion and transformation?

Atmospheric processes profoundly affect ambient air quality. Certain pollutants like photochemical oxidants, nitrogen dioxide, acid aerosols and fine particulate sulfates and nitrates arise principally through atmospheric transformations. The relationship between oxidant precursors and oxidants is a crucial area of uncertainty. This complex relationship can lead to situations that alter reactivity in such a way that oxidant levels at a central city monitoring station could be reduced while oxidant levels at downwind sites on the urban fringe might remain elevated or even increase. There is also substantial disagreement among reputable scientists on the importance and extent of regional variations in the formation of secondary pollutants. Present control plans recognize that background levels of pollutants exist but temprospatial differences in background levels are not considered and no provision has been made to consider the transport of pollutants from one air quality control region to another. Failure to address these emerging problems greatly increases the uncertainty of the efficacy of control strategies.

Other exposures like carbon monoxide and lead derived from fuel additive combustion are maximal where vehicles are concentrated. Use of vehicles equipped with catalytic converters will shift acid aerosol exposures into this category. Likewise, widespread use of manganese additives or turbine seals sloughing nickel could create this type of exposure problem. Such pollutants will reach their highest levels in urban street canyons, along arterial thoroughfares and around complex sources like shopping centers and sports complexes. Meteorologic factors are responsible for dispersing and diluting pollutants which are emitted directly from vehicles or formed in the atmosphere from precursor pollutants emitted from vehicles. Meteorological factors are especially important when considering the frequency and magnitude of short term peak exposures. Most existing analyses have assumed that meteorological factors do not vary appreciably from year to year and have not considered the influence of regional and seasonal differences in altitude, sunlight, temperature, humidity and other parameters.

How well do emissions controls work?

Beginning with the 1968 model year, each new cohort of motor vehicles was equipped with some sort of emissions control system as required by Federal regulations. Thus far emissions controls might be expected to have their greatest impact on carbon monoxide and hydrocarbons with only a modest reduction in nitrogen oxides. Has ambient air quality improved? Our monitoring data are not adequate to answer the question definitively but several hopeful trends are evident. California monitoring data show a reversal of previously upward trends and a substantial reduction in daily maximum carbon monoxide levels. Similarly, peak hourly oxidant levels in cities participating in the EPA continuous air monitoring program have been reduced by roughly 25%. Thus far there are inadequate data to evaluate the effects of recent fuel restrictions on urban air quality. Sufficient information does exist to lead us to conclude that performance of emissions control systems on consumer operated vehicles does deteriorate significantly.

How does one link pollutant emissions to human exposures?

Models linking emissions to human exposure are helpful but crude and often unvalidated. Major problem areas include the influence of human activity patterns, indoor air pollutant levels at home and at work, and our limited understanding of the processes that transform primary pollutants into secondary pollutants. When pollutant exposures involve a large area as in the case with oxidants the problem of constructing an appropriate exposure model will probably prove manageable. Progress is also possible when exposures are largely determined by the proximity of substantial numbers of vehicles, as is the case with carbon monoxide. Then human activity patterns become most important. Control strategies have not adequately considered how human activity influences exposure to carbon monoxide. This failure is especially important because urban exposures manifested by carboxyhemoglobin levels in nonsmokers who donate blood reflect higher carbon monoxide exposure than one would expect from most existing air monitoring data. The most complex situation occurs when emissions from different types of sources and exposures via several environmental media are involved, as is the case with lead. To date only a limited number of investigators have reported studies in which they attempted to establish and utilize human exposure models. Much more work remains to be done if the more obvious major uncertainties are to be reduced.

What should a minimally adequate health intelligence base assess?

A minimally adequate health intelligence base should ascertain the effects of long-term low level exposures and the effects of single or repeated short-term exposures. In general it is easiest to ascertain what acute effects follow short-term fluctuations in air quality. Less complete information is available on the acute and chronic effects which follow long-term low level exposures and very little is known about the chronic effects of peak exposures. The present primary air quality standards usually consider only an annual average or a single short-term averaging time. It is assumed that the necessary air quality controls will also protect against repeated short-term exposures that are less than the standards. This is an untested assumption and further refinement of the standards may prove necessary.

All reasonably expected adverse health effects should be considered when setting a standard. In fact, adverse effects which are postulated but not proven have not always been carefully considered. Failure to consider what is reasonably expected but not yet elucidated ignores a large important area of uncertainty. The effects of air pollutants on respiratory cancers, on the unborn infant and on aging represent three areas of great uncertainty.

The most important expected interactions with other pollutants and with other major determinants of each adverse effect should be determined. In practice, standards based upon community studies do consider pollutant interactions and from a combination of research approaches one may at times assess the relative importance of other determinants of disease. In the case of the automotive pollutants such assessments have not been completed.

Most adverse health effects are best evaluated by blending complementary research approaches. Epidemiology, clinical research and animal toxicology each have their advantages and limitations. Epidemiologic studies are set in the real world and thus allow consideration of the effect of complex long- and short-term pollutant exposures on susceptible segments of the population. However, community studies utilize rather crude health measurements. They must cope with a host of strong covariates and are restricted to a limited range of exposures. Clinical studies utilize more sophisticated health measurements and carefully controlled exposures of human volunteers. Susceptible segments of the population may be studied and many of the bothersome covariates found in community studies may be avoided. However, long-term exposures cannot be easily evaluated. Toxicology studies provide the opportunity to control strong covariates carefully, to utilize a wide range of pollutant exposures and to examine body tissues. Unfortunately, differences between species and lack of appropriate laboratory models for all susceptible segments of the population limit the usefulness of animal studies. Thus, it is apparent that all 3 research approaches may be necessary and that the design of these studies should provide biological bridges between them in terms of exposure levels considered and health indicators utilized. It is rare that this blend of information can be found.

The present information base does not allow construction of good exposure-response functions for each adverse effect. In fact, we must candidly admit significant uncertainties in our estimates of the effects thresholds for each adverse effect associated with each currently regulated ambient air pollutant. Realistically, the best we can do at present is to define "lower boundary," "upper boundary," and "best judgment" estimates for each "no effect" threshold estimate. Hopefully, these 2 boundary assumptions would provide limits for the arena in which reasonable men might disagree. That is, there should be general agreement that pollution levels higher than the upper boundary assumption result in a particular adverse health effect.

Susceptible population segments subject to greater risk include persons with pre-existing diseases which may be aggravated by exposures to elevated levels of pollutants in the ambient air. Some quantitative information is available on the aggravating effects of air pollutants on asthma, chronic obstructive lung disease and chronic heart disease. One could be legitimately concerned about the aggravating effect of air pollutants on a number of other susceptible population segments: persons with hemolytic anemias, patients with cerebrovascular disease, persons with malignant neoplasms, premature infants and patients with multiple handicaps. Little quantitative information exists about the aggravating effect of pollutants on these disorders.

Air pollutants may also increase the risk in the general population for the development of certain disorders. Many if not all of the general population may experience irritation symptoms involving the eyes or respiratory tract during episodic air pollution exposures. Similarly, even healthy members of the general population may experience impaired mental activity or decreased physical performance after sufficiently high pollution exposures. The general population, especially families with young children, is almost universally susceptible to common acute respiratory illnesses including colds, sore throats, bronchitis and pneumonia. Air pollutants can increase either the frequency or severity of these disorders. Personal air pollution with cigarette smoke, occupational exposures to irritating dusts and fumes and possibly familial factors increase the risk of developing chronic obstructive lung disease and respiratory cancers in large segments of our population. Air pollutants can also contribute to the development of these disorders. A few animal studies indicate that air pollutants may also accelerate atherosclerosis.

Examples of Major Unresolved Demographic and Statistical Problems

At least 6 major unresolved demographic and statistical problems hamper efforts to control air pollutants. First, the population at risk should be characterized more precisely. Gross estimates are available for that portion of the general population exposed to elevated levels of one or more air pollutants but much better estimates are needed. A key missing parameter is more accurate assessment of temprospatial variation in air quality for automotive pollutants. Susceptible subgroups within the general population must be identified and better characterized by rational groupings of clinical diagnoses which are located, quantified and described by age, sex, ethnic group and socio-economic status. Defensible health damage functions will require much better information about populations at risk. A second problem involves improving our vital statistics and air monitoring data base so that one can assess the effect of short-term fluctuations in air pollutant levels or fluctuations in daily mortality. At present there is a hiatus of several years in the national vital statistics base needed for this effort. A third problem involves improving the classification of outpatient illnesses so that selective morbidity indices based upon outpatient records can become an integral part of environmental monitoring systems. With few exceptions, the usual types of available morbidity data are difficult to utilize because of nomenclature problems, physician variability, difficulty in specifying denominators for rates and problems in assessing pollutant exposures.

A fourth problem already briefly mentioned is that of developing improved models for estimating past, current and future exposures. Recapitulating prior exposures in a mobile society is especially troublesome as is following cohorts of mobile individuals through rapidly changing exposures. Another vexing facet of the exposure problem is developing techniques to overcome problems posed by a single environmental station and multiple respondents or health sensors. One question of dispute in such cases is whether the respondents should be considered as individual or as a grouped observation. A fifth challenge is to develop improved statistical techniques to deal with repeated measurements on the same subjects, that is the problem of inter-correlated multivariate time series. A final closely related need is to improve statistical techniques to deal with intercorrelated independent variables in health studies.

The Case of Nitrogen Oxides

Nitric oxide emissions from both stationary and mobile sources have increased during the last seven years as a result of growth and as a result of early emissions controls on light duty motor vehicles which reduced carbon monoxide and hydrocarbon emissions but allowed nitrogen oxide emissions to increase. Atmospheric processes transform nitric oxides into two pollutants, nitrogen dioxide and suspended particulate nitrates, that are considered public health problems. Nitrogen oxides also enter into photochemical reactions that produce and scavenge ozone and other photochemical oxidants. Major residual uncertainties which hamper control efforts involve health effects, measurements methods and air monitoring. The atmospheric chemistry of nitrogen oxides, modeling problems and control technology are technical areas that also require more work but they will not be discussed.

Health Intelligence Problem

The limited health intelligence base for nitrogen dioxide leaves little doubt that long-term exposures and repeated short-term exposures to elevated levels of nitrogen dioxide can increase susceptibility to acute respiratory illness and increase the risk of chronic lung disease. There is also ample reason to suspect that other oxides of nitrogen including nitrous acid, nitric acid and suspended particulate nitrates will adversely affect health. Acid aerosols and finely divided particulate nitrates would be expected to aggravate asthma and exacerbate the symptoms of chronic heart and lung diseases. Of equal concern is the possibility that acid aerosols, nitrites and nitrates might increase the risk of respiratory and perhaps gastrointestinal cancers. Actually, there are only a few relevant studies of these problems (see Table 1). There are so many missing pieces in the health data puzzle that one cannot be assured that the present ambient standard protects against the most severe adverse effects. Furthermore, most of the studies upon which the standard is based are community studies. Without accompanying clinical and toxicological studies, community studies usually remain suspect. The other types of studies are required to give a biologically coherent picture and more adequate dose-response relationships.

There is no short-term Federal air quality standard for nitrogen dioxide. Empirical distribution models for cities with continuous air monitoring stations show that the present annual average standard for nitrogen dioxide is roughly equivalent to a 1-hour level of 1400 $\mu g/m^3$. Even this extremely high value is substantially below the best judgment estimates for adverse effects (excluding odor) following short-term exposures (Tables 2 and 3).

Best judgment and boundary estimates

Table 1.—Adverse effects which might be attributed to nitrogen dioxide exposures.

EXPECTED EFFECT	RESEARCH APPROACH		
	EPIDEMIOLOGY	CLINICAL	TOXICOLOGY AT LOW EXPOSURE LEVELS (<9000 $\mu g/m^3$)
INCREASED SUSCEPTIBILITY TO ACUTE RESPIRATORY DISEASE	THREE REPLICATED STUDIES	NO DATA	REPLICATED RODENT STUDIES
INCREASED SEVERITY OF ACUTE RESPIRATORY DISEASE	TWO REPLICATED STUDIES	NO DATA	TWO STUDIES WITH RODENTS
INCREASED RISK OF CHRONIC RESPIRATORY DISEASE	TWO STUDIES SHOW A WORRISOME FINDING OF REDUCED VENTILATORY FUNCTION IN CHILDREN	ANECDOTAL CASE REPORTS	FOUR STUDIES WITH RODENTS
AGGRAVATION OF ASTHMA	ONE STUDY SUGGESTS PARTICULATE NITRATES AGGRAVATE ASTHMA	NO DATA	NO DATA
AGGRAVATION OF HEART AND LUNG DISORDERS	NO DATA	NO DATA	NO DATA
CARCINOGENESIS*	NO DATA	NO DATA	NO DATA
FETOTOXICITY OR MUTAGENESIS	NO DATA	NO DATA	NO DATA

*THROUGH NITRATES OR NITRITES.

Table 2.—Best-judgment exposure thresholds for adverse effects due to nitrogen dioxide (short term).

EFFECT	THRESHOLD, μg/m³
DIMINISHED EXERCISE TOLERANCE	9400 FOR 15 MINUTES
SUSCEPTIBILITY TO ACUTE RESPIRATORY INFECTION	2800 FOR 2 HOURS[a]
DIMINISHED LUNG FUNCTION	3800 FOR ONE HOUR
PRESENT STANDARD	EQUIVALENT TO 1400 μg/m³ FOR ONE HOUR

[a] BASED ON ANIMAL STUDIES ONLY.

for long-term nitrogen dioxide exposures (Tables 4 and 5) are complicated by the need to consider a variety of averaging times. The situation is further clouded by the pivotal nature of community studies conducted in Chattanooga in neighborhoods near the Volunteer Army Arsenal Plant which emitted acid aerosols as well as nitrogen dioxide. Within the uncertainties posed by the available health studies, the existing standard seems adequate with a margin of safety greater than the margin for sulfur oxides and suspended particulates.

Fortunately, other laboratory, clinical and epidemiology studies on the effects of nitrogen dioxide are becoming available. Each of these is needed to improve our scientific information base and all of these studies have thus far indicated that there is a real need to control ambient levels of nitrogen dioxide. If our strong suspicions about the adverse effects attributable to acid aerosols and suspended nitrates are confirmed, more stringent control of nitrogen oxides may be required to protect public health.

Measurement Method Problem

When the Air Quality Criteria Document for Nitrogen Oxides was issued there was no acceptable method for demonstrating the equivalency of two or more measurement methods. The 2 most frequently utilized measurement methods for ambient air were the continuous Griess-Saltzman method and the Jacobs-Hochheiser method which utilized a 24-hour bubbler system. Both methods were internally consistent but they did not agree well with each other. Because the National Air Sampling Network and a series of key health studies utilized the cheaper Jacobs-Hochheiser 24-hour bubbler method, this method was designated as the Federal Reference Method for nitrogen dioxide measurement. Unfortunately, when adequate permeation tubes became available, our laboratories found that the Federal Reference Method was not acceptable because of a variable collection efficiency. This finding required that the Agency designate acceptable alternate monitoring methods and reassess the primary ambient air quality standard for nitrogen dioxide.

When the original Federal Reference Method was retracted, 3 tentative candidate methods were proposed to serve during an interim period while all candidate methods were being thoroughly evaluated. These candidate methods are the continuous chemiluminescent method, the continuous Griess-Saltzman method and the 24-hour arsenite bubbler method. The latter 2 methods depend upon the same diazotization reaction but differ in the pH of the collection media, the elapsed time prior to analysis and the use of a stabilizing agent. The present Air Quality Standard for nitrogen dioxide is based upon an annual average pollutant concentration and both continuous and short-term integrated methods (e.g., 24-hour bubbler methods) can be used to demonstrate achievement of the annual standard. However, if an air quality standard based on a shorter term of exposure is adopted, then a continuous monitoring method will be needed to measure compliance. In that case the 24-hour bubbler methods, which are cheaper and easier to operate, can be used to identify problem areas requiring continuous monitors and to satisfy some implementation plan needs.

Let me briefly summarize our current information about the measurement of nitrogen dioxide. First, the recently retracted Federal Reference Method which assumed a constant collection efficiency of 35% is not tenable because the true collection efficiency is very high at low concentrations of nitrogen dioxide and

Table 3.—Threshold estimates for adverse health effects attributable to nitrogen dioxide (short term).

Adverse Effect	Research Approach	Type of Estimate	Exposure		Safety Margin ( )* Contained in Primary Standard (1400 ug/m^3 equivalent)
			Level ug/m^3	Duration	
Odor Perception	Clinical	Worst Case	225	5 minutes	None
		Least Case	835	3 minutes	None
		Best Judgment	225	5 minutes	None
Diminished exercise tolerance	Clinical	Worst Case	1900	15 minutes	36**
		Least Case	14500	6 hours	936**
		Best Judgment	9400	15 minutes	571**
Susceptibility to acute respiratory infection	Toxicology	Worst Case	2800	2 hours	100
		Least Case	28200	3 hours	1900
		Best Judgment	2800	2 hours	100
Diminished Lung function	Clinical	Worst Case	3000	1 hour	114
		Least Case	9400	15 minutes	571**
		Best Judgment	3800	1 hour	171
Fatality	Toxicology	Worst Case	165,000	4 hours	11,685
		Least Case	940,000	1-2 hours	67,043
		Best Judgment	188,000	1 hour	13,329

*Safety Margin = Effects threshold minus standard divided by standard x 100.
**Assumes hourly exposure at same level

Table 4.—**Best-judgment exposure thresholds for adverse effects due to nitrogen dioxide (long term).**

EFFECT	THRESHOLD, μg/m³*
INCREASED SUSCEPTIBILITY TO ACUTE RESPIRATORY INFECTION	188
INCREASED SEVERITY OF ACUTE RESPIRATORY DISEASE	141
INCREASED RISK OF CHRONIC RESPIRATORY DISEASE	470**
DECREASED LUNG FUNCTION	188
PRESENT STANDARD	100 μg/m³ ANNUAL AVERAGE

*ANNUAL AVERAGE EQUIVALENT.

**BASED SOLELY ON ANIMAL STUDIES.

quite low at high concentrations (Fig. 1). Since nitrogen dioxide concentrations may vary a great deal during the 24-hour sampling period there is no easy way to adjust for a variable collection efficiency over a 24-hour sampling period. Ignoring the latter problem, the usual result of the variable collection efficiency error would be to underestimate the true exposures at concentrations greater than 120 $\mu g/m^3$ and overestimate exposures at lower levels. In general the shape of the collection efficiency curve suggests that the overestimation problem would be more severe. Another problem is that nitric oxide has proved to cause a significant positive interference with the retracted method.

Our laboratories are evaluating 5 other measurement methods including the 3 tentative candidate methods previously mentioned. This evaluation should allow our Agency to designate a scientifically defensible measurement method and to relate that method to the continuous Saltzman method and to the arsenite bubbler method. The latter task is necessary because the Saltzman method was employed in many of the health studies upon which the primary standard was based and because the major portion of our meager national air monitoring data base depends upon the arsenite method. In brief, it seems that the continuous Saltzman method may have problems in that measurements at low ambient concentrations are unreliable and ozone exerts a worrisome negative interference. A number of investigators outside of government disagree with us and feel that the Saltzman method is quite reliable. The arsenite bubbler method has a stable 85% collection efficiency over a wide range of nitrogen dioxide concentrations. However, interferences caused by gases commonly present in urban air handicap this method: carbon dioxide causes a positive interference and nitric oxide a negative interference. These worrisome interferences vary depending on the absolute concentrations of the interfering gases and the ratio of their concentration to that of nitrogen dioxide. The triethanol amine guaicol sulfite (TGS) method appears quite promising even though it is not one of the 3 proposed candidate methods. The TGS method has a stable 93% collection efficiency. No interferences caused by ambient pollutants have been identified and the collection media has good stability after sampling. The continuous chemiluminescent method avoids many of the problems inherent in wet chemical procedures but most instruments thus far evaluated either suffer from early production problems or require highly qualified field operators. However, the chemiluminescent approach retains a great deal of promise. To establish a new reliable reference method which is properly standardized and field tested will require another year with collaborative field testing occupying at least 6–9 months.

Air Monitoring Data

When nitrogen dioxide levels in ambient air were measured at 196 sites using two 24-hour bubbler methods, the former Federal Reference Method and the arsenite method, it was apparent that the Federal Reference Method, which assumed a constant 35% collection efficiency, resulted in readings that were more than twice as high as those obtained by the arsenite method with an assumed constant 85% collection efficiency. This relationship was observed in several sites that had annual average arsenite readings which were just below or just above the primary ambient air quality

Table 5.—Threshold estimates for adverse health effects attributable to nitrogen dioxide (long term).

Adverse Effect on Human Health	Research Approach	Type of Estimate	Exposure: Level ug/m3	Exposure: Duration	Safety Margin ( )* Contained in Primary Standard: Annual Average Equivalent	(100 ug/m3)
Increased susceptibility to acute respiratory infection	Epidemiology	Worst Case	188 564 376	For ten percent** of hrs. or days for 3 yrs. or less	(94) (282) (188)	None 182 83
	Toxicology	Worst Case Least Case Best Judgment	940 9400 940	3 months 3 months 3 months		20 to 400 9300 50
Increased severity of acute respiratory disease	Epidemiology	Worst Case Least Case Best Judgment	188 470 282	For ten percent** of hrs. for at least 1 year.	(94) (235) (141)	None 135 41
	Toxicology	Worst Case Least Case Best Judgment	940 3760 940	For 6 or more hrs. each day for 3 or more months		840 3660 840
Increased frequency of chronic respiratory disease symptoms	Epidemiology	Point Estimate	No increase after 3 years exposure to levels between 188 ug/m3 and 564 ug/m3 on ten percent of hours or days		Not Applicable	
	Toxicology	Worst Case	940 3800 940	For 6 hrs. or more each day for 3 months or more	(470) (1900) (470)	370 1800 370
Decrease Lung Function	Epidemiology	Worst Case Least Case Best Judgment	188 564 376	For ten percent of hrs. for 3 years or less	(94) (282) (376)	None 182 276
Aggravation** of Chronic heart and lung diseases			NO DATA			
Carcinogenesis**			NO DATA			
Fetotoxicity and** Mutagenesis			NO DATA			

*Safety Margin = Effects threshold minus standard divided by standard x 100.
**Through either nitrogen dioxide or nitrous acid - nitric acid - nitrate route.

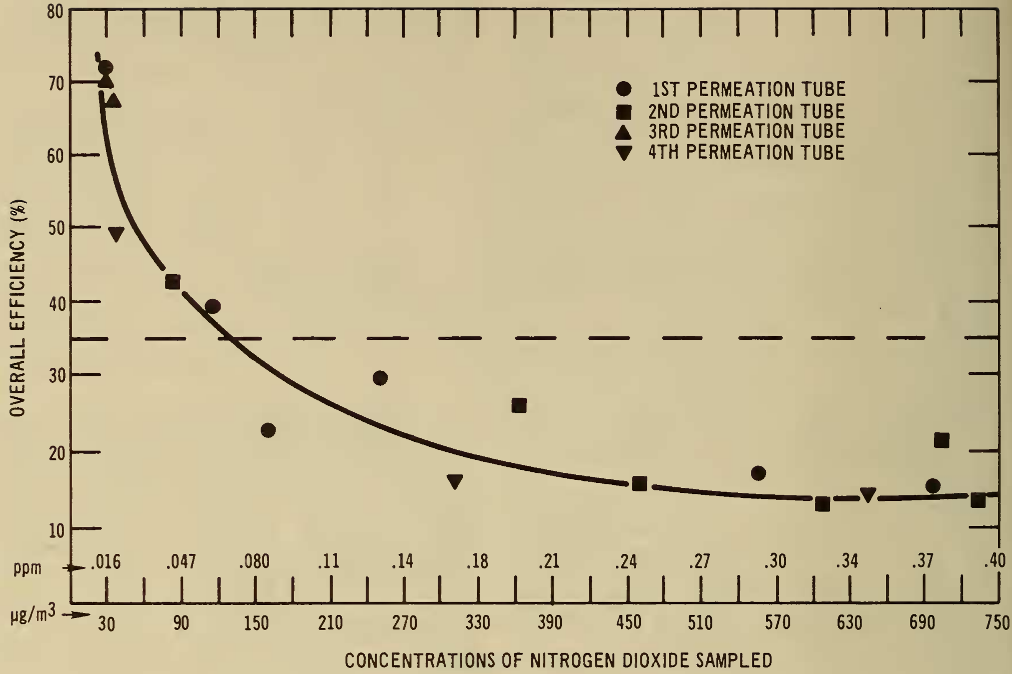
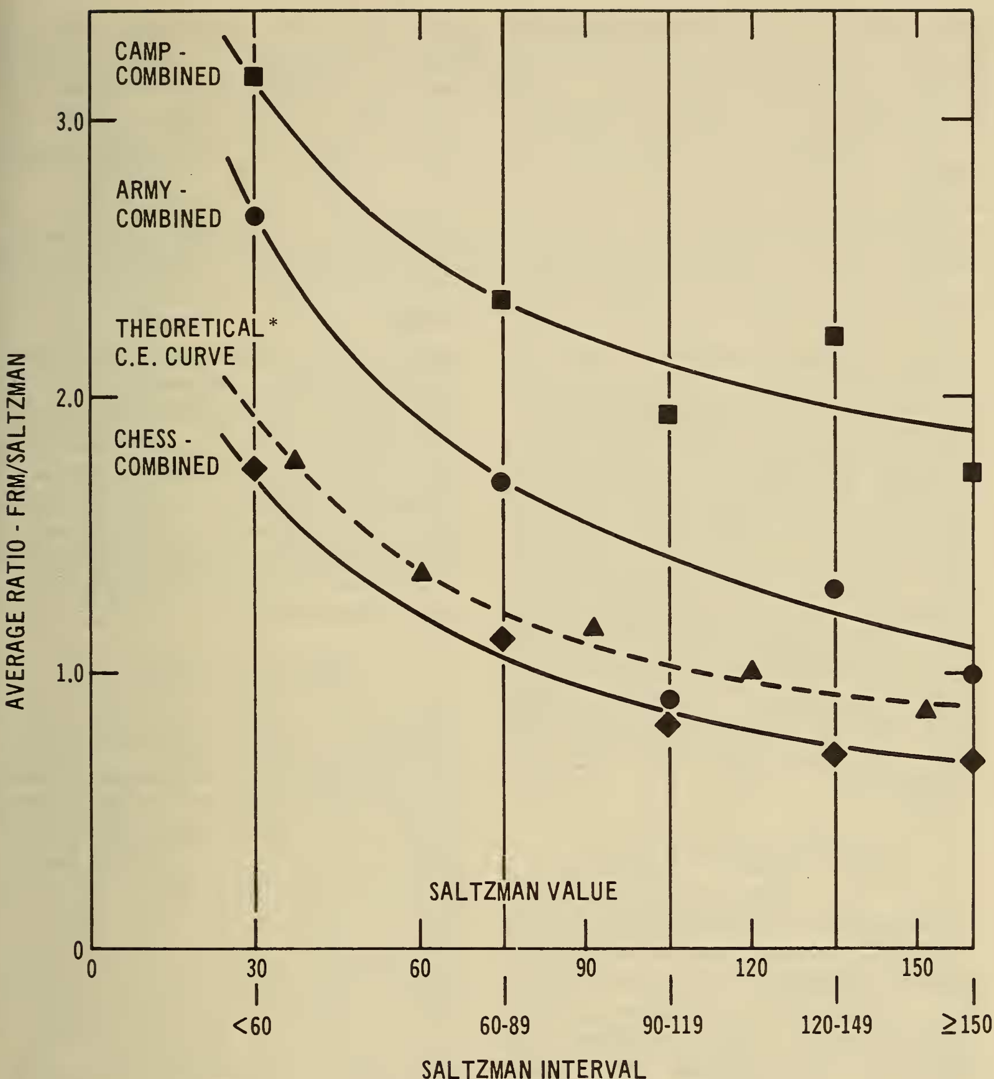


Fig. 1.—Response to the NO_2 reference method.

standard. Such sites were located in Los Angeles, Chicago, New York and Baltimore. A somewhat lower ratio of 1.6 between a slightly modified version of the Federal Reference Method and the arsenite method was obtained at 7 sites in Chattanooga, California and St. Louis by the same group of Federal investigators who conducted the Chattanooga School health studies of nitrogen dioxide 3 years prior to these recent aerometric studies. When the ratio between the continuous Saltzman and Federal Reference Methods (FRM) was compared, the Federal Reference Method was 2.6 times higher in the 6 continuous air monitoring stations which are part of the same operation that maintained the National Air Sampling Network. When similar data from 3 stations operated by the investigators conducting health studies were compared a ratio of only 1.4 was observed. Interestingly enough, almost the same difference in FRM to Saltzman ratios, 3.1 vs. 1.5, was noted when these 2 groups operated stations in close proximity in the same city. In the critical region for health effects, that is between 90 and 149 $\mu g/m^3$, the Federal Reference Method in the hands of the health investigators gave readings that were about 20% lower than the Saltzman method, whereas Federal Reference Method readings from the continuous air monitoring program were more than twice as high as Saltzman readings. Fortunately, it was also possible to compare Federal Reference Method readings made by the health investigators in Chattanooga with Saltzman readings made at a nearby site by the U.S. Army. Overall and within the critical concentration range, the Federal Reference Method to Saltzman ratios were intermediate, being higher than those observed by the health group and lower than those found in the continuous air monitoring program. These relationships, seen in Fig. 2, can be compared with what one would expect given the theoretical collection efficiency curve and assuming that there was no significant diurnal variation in nitrogen dioxide. This analysis explains why the Federal Reference Method appeared so



*BASED ON EFFICIENCY CURVE OF FRM. THIS CURVE REPRESENTS THE EXPECTED EFFECT ON THE RATIOS BETWEEN THE TWO METHODS IGNORING THE EFFECTS OF INTERFERENTS AND EMPIRICAL METHODOLOGICAL VARIABILITY.

Fig. 2.—FRM FRM/Saltzman ratio vs. Saltzman interval.

much higher than the Saltzman method in cities participating in the continuous air monitoring program. More importantly, the analysis points out the need for a strong quality assurance program for air quality measurements. The foregoing analysis also helps explain why the Federal Reference Method happens to give a fair approximation of Saltzman measurements in Chattanooga during the Chattanooga health studies but a poor approximate elsewhere. A re-analysis of these health studies using only Saltzman measurements will be discussed later.

Another legitimate question is to ask

how well the 3 tentative candidate methods compare with one another. The continuous Saltzman method operated by the continuous air monitoring program (CAMP) compares fairly well with the arsenite method except when nitrogen dioxide concentrations are very low. In the former case the ratio between the 2 methods ranged between 0.8 and 1.2 with a correlation coefficient of greater than 0.8. The ratios were higher (1.2 to 1.5) and the correlation poorer when the Saltzman method was used by our health investigators. The continuous Saltzman and chemiluminescent methods were also compared and the health investigators seemed to get a better relationship with ratios of 1.1 to 1.4 than did the CAMP program ratios of 0.7 to 1.3. Unfortunately in this comparison the correlation coefficients were quite variable—0.3 to 0.8—for both groups. One can thus state little more than that the 3 methods seem roughly comparable in field settings and that the planned standardization and quality assurance programs are clearly needed.

The Case of the Oxidation Catalyst

One way to reduce the amounts of carbon monoxide and unburnt hydrocarbons emitted by current sparkfired internal combustion engines is to pass exhaust steam through an oxidation catalyst which converts these pollutants to harmless carbon dioxide and water. Work with oxidation catalysts began over a decade ago and this course was chosen by major U.S. auto manufacturers four years ago. Catalysts-equipped vehicles require low phosphorous, lead-free fuels because these substances adversely affect catalyst performance. Current legislation requires that automobile manufacturers develop control technology for reducing automotive emissions but the pathway and time frame for assuring that control devices pose no public health problem is less clear. At any rate, health problems could arise from undesirable thermal effects of improperly shielded catalytic converters, the emission of catalyst attrition products or the ability of catalysts to alter unregulated mobile source emissions. Catalysts are scheduled to be installed on 1975 model year vehicles. A vigorous research program is underway to assess what health trade-offs might be involved. Major certainties involve emission levels of catalyst attrition products and acid aerosols, dispersion of these pollutants, the magnitude of the resulting personal exposures and the expected adverse effects. Research programs in the Federal Government and in industry should avoid similiar problems in the future by making safety assurance an integral part of the research and development effort devoted to any control technology.

Summary and Conclusions

Protection of public health and existing legislative mandates require that automotive emissions of carbon monoxide, hydrocarbons, oxides of nitrogen and a number of currently unregulated emissions be reduced to acceptable levels. Scientific uncertainty makes the task extremely difficult and contributes to public acrimony. Unrestrained advocacy hampers efforts to reveal existing information, reduce uncertainty and avoid emerging problems. Despite these societal and other technical difficulties progress is being made in that air quality is beginning to improve. Case studies of nitrogen oxides and catalytic converters illustrate the interrelationship between major technical components required by a rational control effort. Shifting from the present "no-effect" threshold risk philosophy to a cost-benefit risk philosophy would only intensify the impact of technical uncertainties. The most rational approach is to unite and intensify governmental and private efforts to reduce bothersome scientific uncertainty to more acceptable levels.